PEDITRACE- zinc chloride, cupric chloride, manganese chloride, sodium selenite, sodium fluoride and potassium iodide injection, solution
Fresenius Kabi USA, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Peditrace

1 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of PEDITRACE contains:

Active ingredients	Quantity
Zinc chloride	521 µg
Copper chloride $2H_2O$	53.7 µg
Manganese chloride $4H_2O$	3.60 µg
Sodium selenite anhydrous	4.38 µg
Sodium fluoride	126 µg
Potassium iodide	1.31 µg

The active ingredients in 1 ml of PEDITRACE correspond to

Zn	250 µg	3.82 µmol
Cu	20 µg	0.315 µmol
Mn	1 µg	18.2 nmol
Se	2 µg	25.3 nmol
F	57 µg	3.00 µmol
I	1 µg	7.88 nmol

The contents of sodium and potassium correspond to

Sodium	70 µg	3.05 µmol
Potassium	0.31 µg	7.88 nmol

For excipients, see 5.1.

PRODUCT PROPERTIES

- Osmolality 38 mosm/kg water
- pH: 2.0

2 PHARMACEUTICAL FORM

Concentrate for solution for infusion

3 CLINICAL PARTICULARS

3.1 Therapeutic indications

PEDITRACE is indicated in premature and full-term infants and children needing intravenous nutrition to supply the basal requirements of trace elements.

3.2 Posology and method of administration

PEDITRACE must not be given undiluted.

The recommended dose is 1 ml PEDITRACE/kg body weight/day for infants and children with a weight of up to 15 kg. The basic requirements of trace elements are covered by a daily dose of 15 ml to children weighing more than 15 kg.

3.3 Contraindications

Wilson's Disease.

3.4 Special warnings and special precautions for use

PEDITRACE should be used with caution in patients with impaired biliary and/or renal function, in whom the excretion of trace elements may be significantly decreased.

PEDITRACE should also be used with caution in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis).

If the treatment is continued for more than 4 weeks, checking of manganese levels is required.

Patients with increased losses or requiring prolonged intravenous nutrition should be monitored biochemically to confirm the requirements are being met appropriately.

3.5 Interaction with other medicinal products and other forms of interaction

No interactions with other drugs have been observed.

3.6 Pregnancy and lactation

Not applicable.

3.7 Effects on ability to drive and use machines

Not applicable.

3.8 Undesirable effects

No adverse effects related to the trace elements in PEDITRACE have been reported.

Superficial thrombophlebitis has been observed when glucose containing PEDITRACE was given. However, it is not possible to deduce whether this reaction is attributable to the trace elements infusion or not.

Allergic reactions to iodine may occur following topical application. No adverse reactions are known to occur as a consequence of using the recommended intravenous iodide dosage levels.

3.9 Overdose

In patients with impaired renal or biliary function, there is an increased risk for accumulation of trace elements.

4 PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

PEDITRACE is a mixture of trace elements in amounts normally absorbed from the oral diet and should have no pharmacodynamic effect besides maintaining or repleting nutritional status.

4.2 Pharmacokinetic properties

When infused intravenously the trace elements in PEDITRACE are handled in a similar way to trace elements from an oral diet. Individual trace elements will be taken up by tissues to different extents, depending on the requirement within each tissue to maintain or restore the concentration of each element for the metabolic requirement of that tissue.

Copper and manganese are normally excreted via the bile, whereas selenium and zinc (especially in patients receiving intravenous nutrition) are mainly excreted via the urine.

4.3 Preclinical safety data

The safety evaluation is based mainly on clinical experience and documentation.

5 PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Hydrochloric acid

Water for injections

5.2 Incompatibilities

PEDITRACE may only be added to or mixed with other medicinal products for which compatibility has been documented. See 5.6.

5.3 Shelf‑life

3 years.

5.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

5.5 Nature and content of container

Vial for injection, polypropylene plastic.

Pack size: 10 x 10 ml

5.6 Instructions for use and handling

COMPATIBILITY

Additions should be made aseptically.

Additions

Up to 6 ml PEDITRACE can be added to 100 ml Vaminolact, Vamin 9 Electrolyte Free, Vamin 14 Electrolyte Free or glucose solution (50-500 mg/ml).

INFUSION TIME

The infusion time should not be less than 8 hours. The infusion should be given at a very slow rate.

STABILITY

When additions are made to an infusion solution, the infusion should be completed within 24 hours from preparation to prevent microbiological contamination. The left-over contents of opened

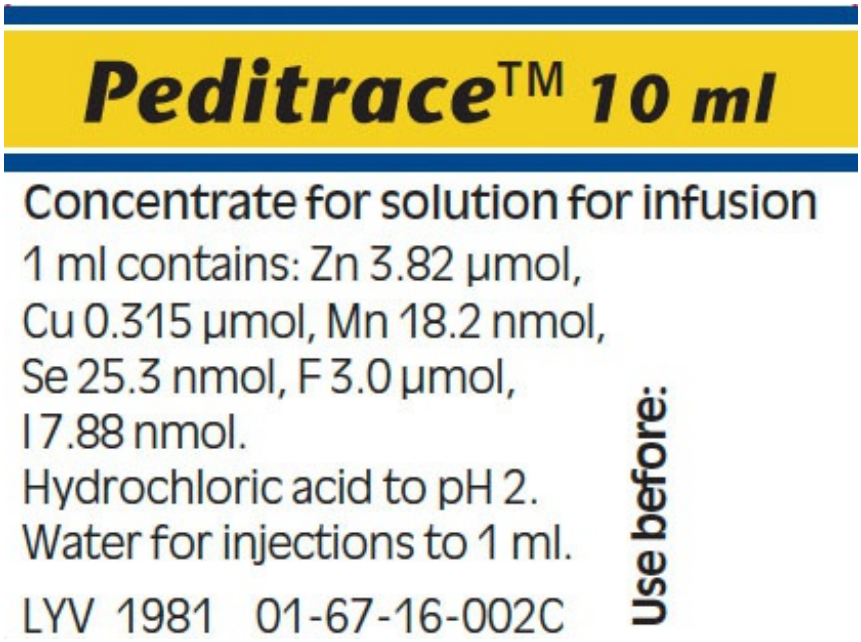
bottles/vials/ampoules should be discarded and not kept for later use.

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - Peditrace 10 mL Vial Label

Peditrace™

10 ml

Concentrate for solution for infusion

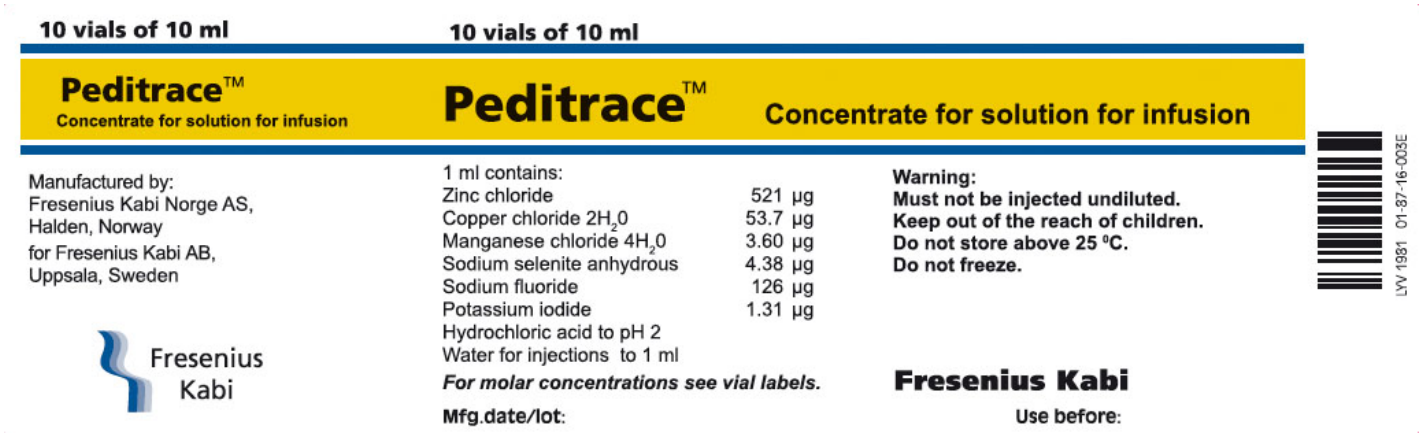


PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - Peditrace 10 mL Vial Carton Panel

10 vials of 10 ml

Peditrace™

Concentrate for solution for infusion



PEDITRACE

zinc, copper, manganese, selenium, fluorine, and iodine injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-147
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	250 ug in 1 mL
CUPRIC CHLORIDE (UNII: S2QG84156O) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	20 ug in 1 mL
MANGANESE CHLORIDE (UNII: QQE170PANO) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	1 ug in 1 mL
SODIUM SELENITE (UNII: HIW548RQ3W) (SELENITE ION - UNII:KXO0259XJ1)	SELENITE ION	2 ug in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	57 ug in 1 mL
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	1 ug in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM (UNII: 9NEZ333N27)	70 ug in 1 mL
POTASSIUM (UNII: RWP5GA015D)	0.31 ug in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63323-147-10	10 in 1 CARTON		
1		10 mL in 1 VIAL, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		05/09/2013	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Norge AS		731170932	MANUFACTURE(63323-147)

Revised: 5/2013 Fresenius Kabi USA, LLC